Nplate®
Hospital Billing and Coding Information

Nplate® romiplostim injection

Nplate® is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Nplate® is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than chronic ITP. Nplate® should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Nplate® should not be used in an attempt to normalize platelet counts.

Item	Revenue Code[1,2]	Coding Information (HCPCS[3]/CPT[4]/ICD-10-CM[5])	Notes
Nplate®	**Medicare:** 0636, drugs requiring detailed coding[6] **Other Payers:** 0250, general pharmacy; **OR** 0636, if required by a given payer[6]	J2796, injection, romiplostim, 10 mcg	Nplate® is supplied in single-use vials containing 250 mcg and 500 mcg deliverable romiplostim The NDC numbers for Nplate®, in the 11-digit format, are as follows: - 250-mcg vial: 55513-0221-01 - 500-mcg vial: 55513-0222-01
Administration	Appropriate revenue code for the cost center in which the service is performed	96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	
Diagnosis/ Condition	N/A	Appropriate ICD-10-CM code(s) for patient condition	**Example:** D69.3 Immune thrombocytopenic purpura

1. Value Healthcare Services. Understanding Hospital Revenue Codes. 2017. Available at: http://valuehealthcareservices.com/education/understanding-hospital-revenue-codes/. Accessed November 1, 2017.
2. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual - Chapter 25. Completing and Processing the Form CMS-1450 Data Set. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf. Accessed November 6, 2017.
3. Centers for Medicare & Medicaid Services. 2015 Alpha-Numeric HCPCS File. Available at: http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2015-Alpha-Numeric-HCPCS-File-%C2%A0.html. Accessed November 6, 2017.
4. American Medical Association. Current Procedural Terminology (CPT®) copyright 2014 American Medical Association. 2015. All Rights Reserved.
5. Centers for Medicare & Medicaid Services. 2018 ICD-10-CM Tabular List of Diseases and Injuries. Available at: http://www.cdc.gov/nchs/icd/icd10cm.htm#icd2016. Accessed November 6, 2017.
6. Centers for Medicare & Medicaid Services. Publication 100-04: Medicare Claims Processing Manual, Chapter 17: Drugs and Biologicals, Section 80.9: Required Modifiers for ESAs Administered to Non-ESRD Patients 2017. Available at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf. Accessed November 6-2017.

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this section be considered a guarantee of coverage or reimbursement for any product or service.

IMPORTANT SAFETY INFORMATION

Risk of Progression of Myelodysplastic Syndromes to Acute Myelogenous Leukemia

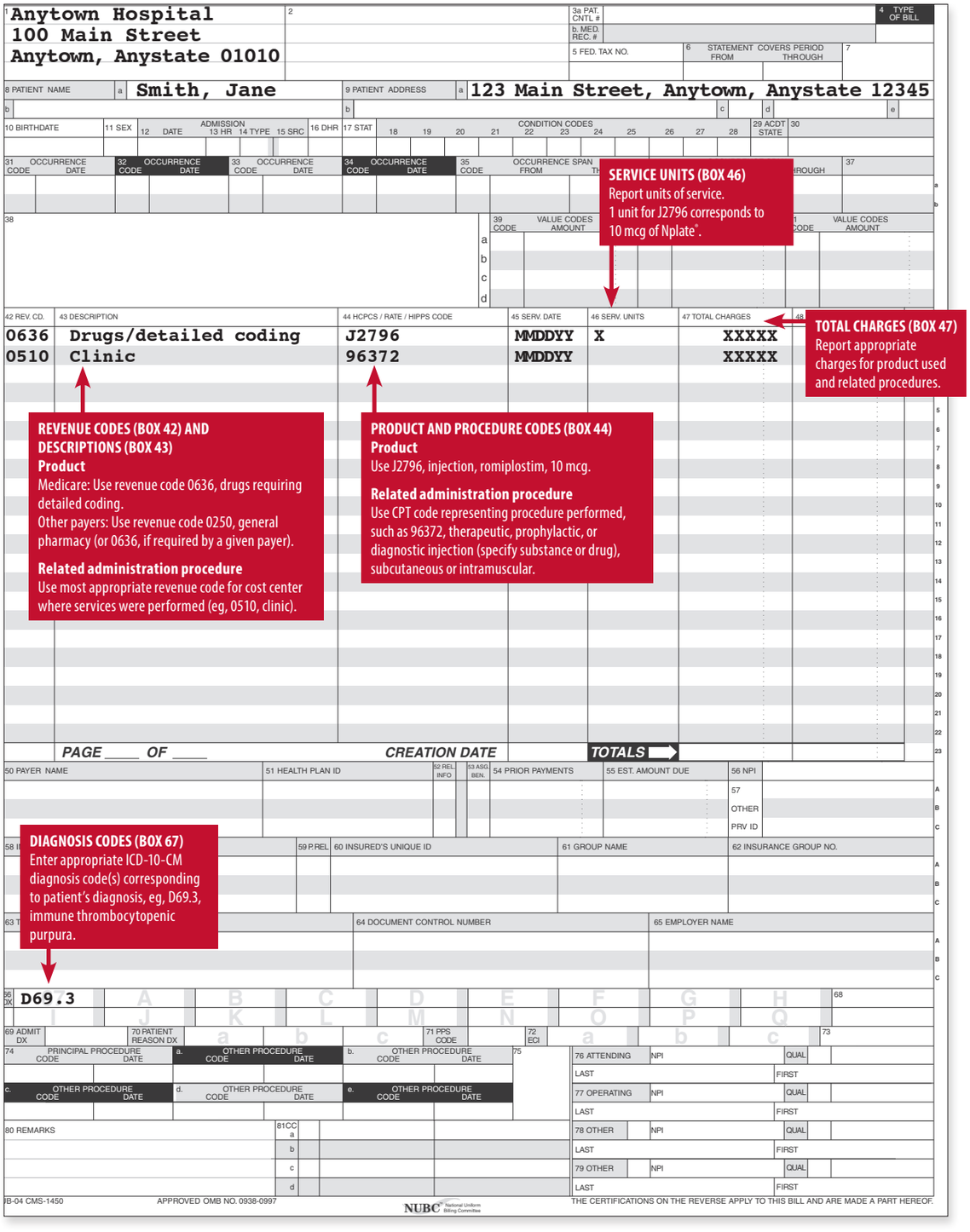
- In Nplate® clinical trials of patients with myelodysplastic syndromes (MDS) and severe thrombocytopenia, progression from MDS to acute myelogenous leukemia (AML) has been observed.
- Nplate® is not indicated for the treatment of thrombocytopenia due to MDS or any cause of thrombocytopenia other than chronic ITP.

Contact Amgen Assist® at 1-888-4ASSIST for assistance.
www.AmgenAssistOnline.com

Please see additional Important Safety Information on page 4.

The CMS 1450 for Hospital Outpatient

Sample UB-04 (CMS 1450) Form — Hospital Outpatient Administration



This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

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Thrombotic/Thromboembolic Complications

- Thrombotic/thromboembolic complications may result from increases in platelet counts with Nplate® use. Portal vein thrombosis has been reported in patients with chronic liver disease receiving Nplate®.
- To minimize the risk for thrombotic/thromboembolic complications, do not use Nplate® in an attempt to normalize platelet counts. Follow the dose adjustment guidelines to achieve and maintain a platelet count of $\geq 50 \times 10^9$/L.

Loss of Response to Nplate®

- Hyporesponsiveness or failure to maintain a platelet response with Nplate® should prompt a search for causative factors, including neutralizing antibodies to Nplate®.
- To detect antibody formation, submit blood samples to Amgen (1-800-772-6436). Amgen will assay these samples for antibodies to Nplate® and thrombopoietin (TPO).
- Discontinue Nplate® if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks at the highest weekly dose of 10 mcg/kg.

Laboratory Monitoring

- Obtain CBCs, including platelet counts, weekly during the dose adjustment phase of Nplate® therapy and then monthly following establishment of a stable Nplate® dose.
- Obtain CBCs, including platelet counts, weekly for at least two weeks following discontinuation of Nplate®.

Adverse Reactions

- In the placebo-controlled trials, headache was the most commonly reported adverse drug reaction, occurring in 35% of patients receiving Nplate® and 32% of patients receiving placebo. Headaches were usually of mild or moderate severity.
- Most common adverse reactions ($\geq$ 5% higher patient incidence in Nplate® versus placebo) were Arthralgia (26%, 20%), Dizziness (17%, 0%), Insomnia (16%, 7%), Myalgia (14%, 2%), Pain in Extremity (13%, 5%), Abdominal Pain (11%, 0%), Shoulder Pain (8%, 0%), Dyspepsia (7%, 0%), and Paresthesia (6%, 0%).
- Nplate® administration may increase the risk for development or progression of reticulin fiber formation within the bone marrow. This formation may improve upon discontinuation of Nplate®. In a clinical trial, one patient with ITP and hemolytic anemia developed marrow fibrosis with collagen during Nplate® therapy.

Women who become pregnant during Nplate treatment are encouraged to enroll in Amgen's Pregnancy Surveillance Program. Patients or their physicians should call 1-800-77-AMGEN (1-800-772-6436) to enroll.

Please click here for full Nplate® Prescribing Information and Medication Guide.

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